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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,374	03/29/2007	Kyu Chan Kwon	CMT-0034	9097

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EXAMINER	
DEBERRY, REGINA M	
ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
09/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,374	KWON ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

Claims 1-11 are under examination.

Priority

Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papadimitriou, US Patent 6,867,182 B2 in view of Yamazaki et al. (reference submitted Applicant; EP 0 909 564 B1) and Cheung et al., WO 00/61169 (reference submitted by Applicant).

Papadimitriou teaches aqueous pharmaceutical compositions comprising a pharmaceutically effective polypeptide. Papadimitriou teaches a composition comprising an aqueous buffered solution having erythropoietin (EPO) and an amphiphilic agent. The concentration of EPO is from 0.1 to 10 mg/ml. The buffer is present in the solution at a concentration from 10 to 500 mmol/liter in solution (column 2, lines 5-17, lines 40-52 and column 7, lines 15-23). Buffers reagents include a phosphate buffer at pH 7.4 (column 4, line 10)(**applies to claim 10**). Papadimitriou teaches that it is preferable for the production of the pharmaceutical composition to add isotonic reagents such as sodium chloride, sugar alcohols such as mannitol (20-100 mg/ml)(**applies to claim 8**), neutral amino acids such as glycine and/or polyhydric alcohols such as polyethylene glycerol (column 6, line 61-column 7, line 2)(applies to claim 3).

The teachings of Papadimitriou are described above. Papadimitriou does not teach EPO formulations comprising polysorbate-based non-ionic surfactants or poloxamer-based non-ionic surfactants. Papadimitriou does not specifically state if EPO is human, recombinant or native.

Yamazaki et al. teach EPO pharmaceutical formulations. The EPO can be human or recombinant EPO (0014). Yamazaki et al. teach aqueous EPO formulations comprising 100 to 500,00 IU/ml of EPO, polyethylene glycol, mannitol, sodium chloride,

phosphate buffer, polysorbate-based non-ionic surfactants such as polysorbate 20 or polysorbate 80(0.01 to 1 mg/ml)(paragraphs 0018-0020)(**applies to claims 5 and 11**) and neutral amino acid such as leucine (paragraphs 0028-0029).

Cheung et al. teach aqueous pharmaceutical formulations comprising EPO (in a range of 1 to 500 IU/kg body)(page 4, lines 10-19; pages 11-12 and claims), polysorbate 20 or polysorbate 80 (in a range of 0.01 to about 1.0 mg per ml), glycine (in a range of 0.1 g/l to 50 g/l)(page 8 and claims), mannitol and sodium chloride (page 7 and claims). Cheung et al. teach the use/amounts of sodium chloride, sodium phosphate (page 7, lines 4-13; pages 8-9, Table A and claims).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an aqueous pharmaceutical formulation comprising an effective amount of EPO, phosphate buffer, sodium chloride, mannitol, glycine and polyethylene glycerol as taught by Papadimitriou, by formulating it with polysorbate 20 or polysorbate 80, as taught by Yamazaki et al. using ranges/amounts taught by Cheung et al. (and Papadimitriou and Yamazaki) with a reasonable expectation of success. The motivation and expected success is provided by Papadimitriou, Yamazaki et al. and Cheung et al., in that all of the inventors teach stable aqueous pharmaceutical formulations comprising EPO, isotonic reagents, neutral amino acids, polyhydric alcohols and/or polysorbate-based non-ionic surfactants. One of ordinary skill in the art of making EPO aqueous formulations would have been motivated to discern the most favorable amounts of each ingredient by adjusting ranges, concentrations, pH, temperature, solubility, time, etc. because these modifications are deemed a matter of

judicious selection and routine optimization which is well within the purview of the skilled artisan.

Applicant is reminded that KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. Please see the recent Board decision Ex parte Smith, USPQ2d, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396). All of the elements parts in the instant composition are disclosed in Papadimitriou, Yamazaki et al. and Cheung et al. All of the added ingredients are known in the prior art for being stabilizers, adsorption preventing agents, pH buffers, isotonic adjusting agents, etc. The only difference is the combination of various amounts of the ingredients into an "old well-known single composition".

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

/R. M. D./
Examiner, Art Unit 1647
9/15/08